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None

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(54) **External fixator device**

(57) An external fracture fixation apparatus comprises an elongate support 2 carrying a plurality of pin mounting blocks 3, the support including an integral strain gauge 5. A universal pin mounting block is mounted on the support element for receiving a fixator pin in a manner which permits variation of the orientation of the pin relatively to the mounting block and which permits rotation of the pin about the longitudinal axis of the support element, locking means being provided for securing the pin with respect to the support element in a selected orientation.

FIG. 1

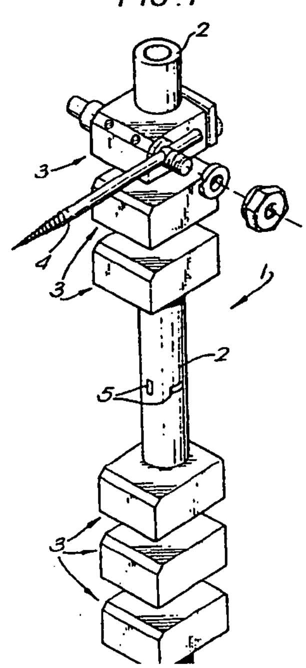

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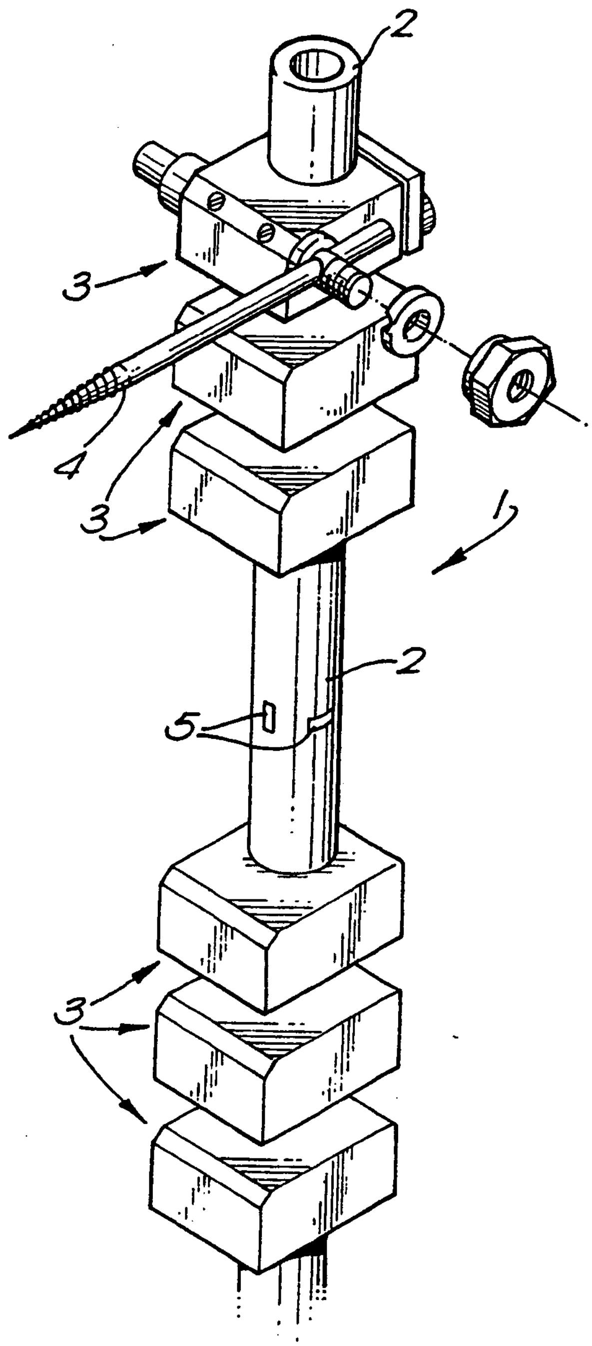
FIG. 1



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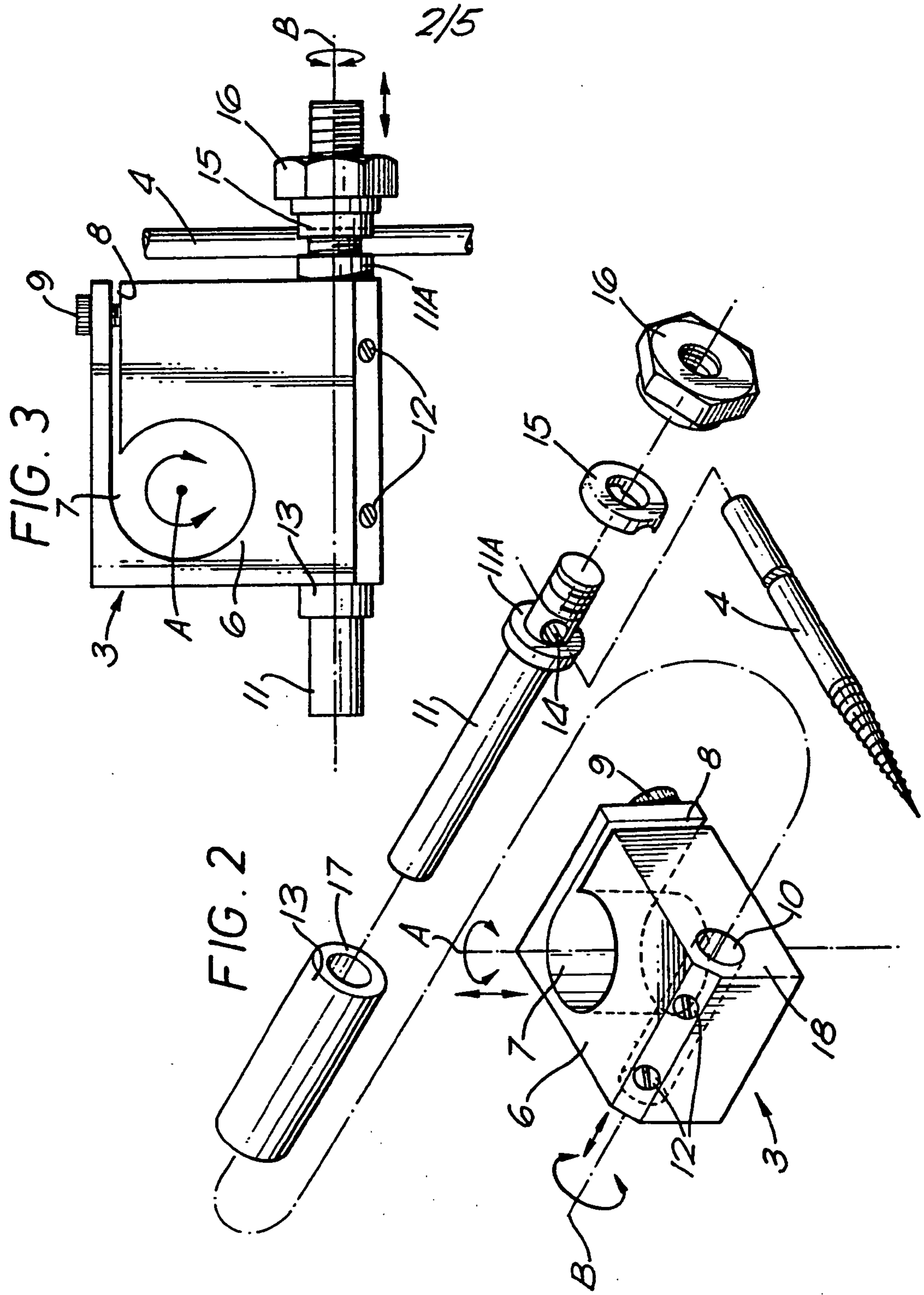

FIG. 3

FIG. 2

FIG. 4 PRIOR ART

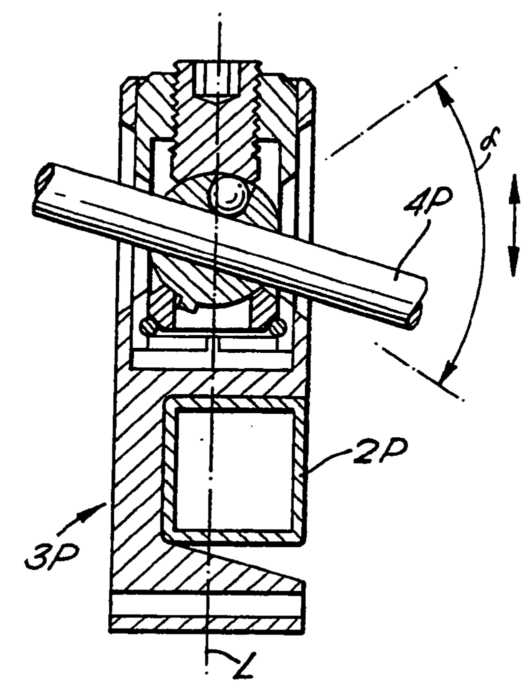

FIG. 5

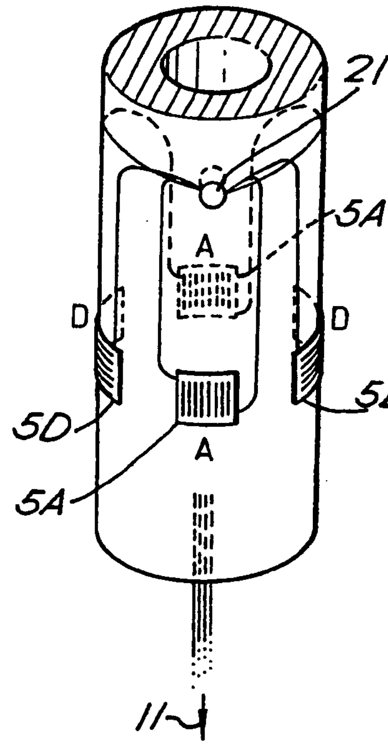

FIG. 6

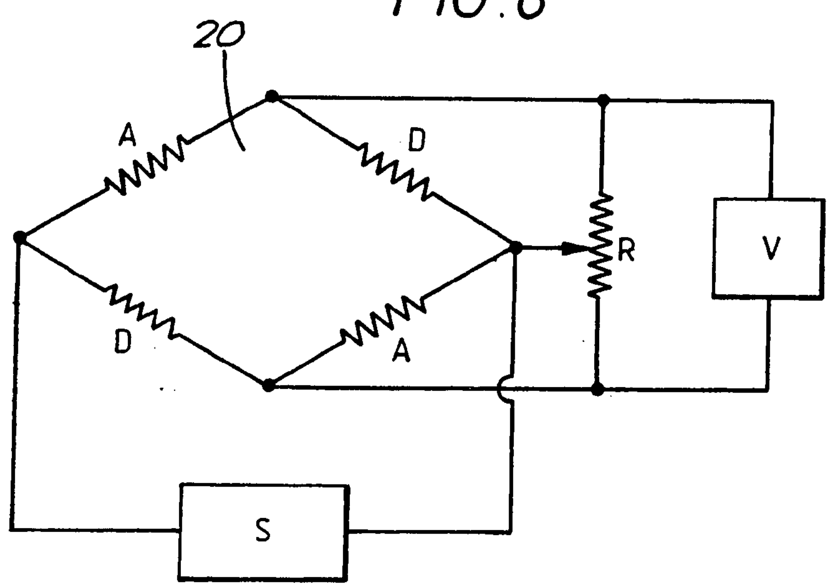

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FIG. 7

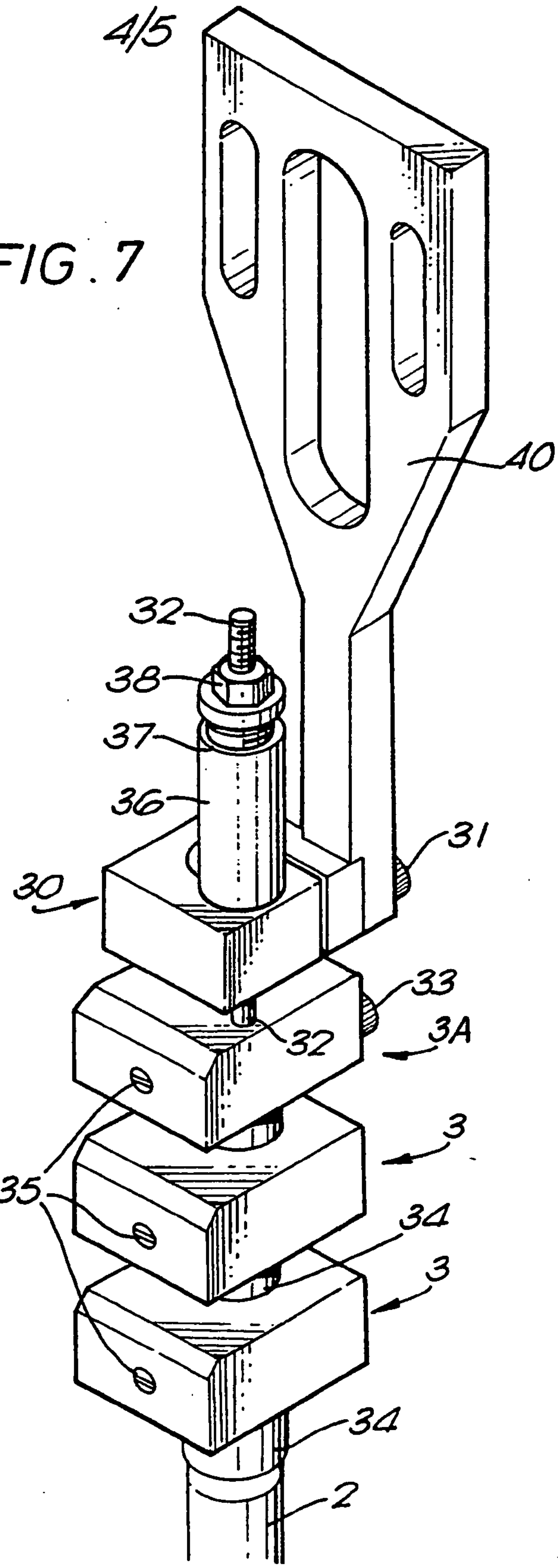

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FIG. 8

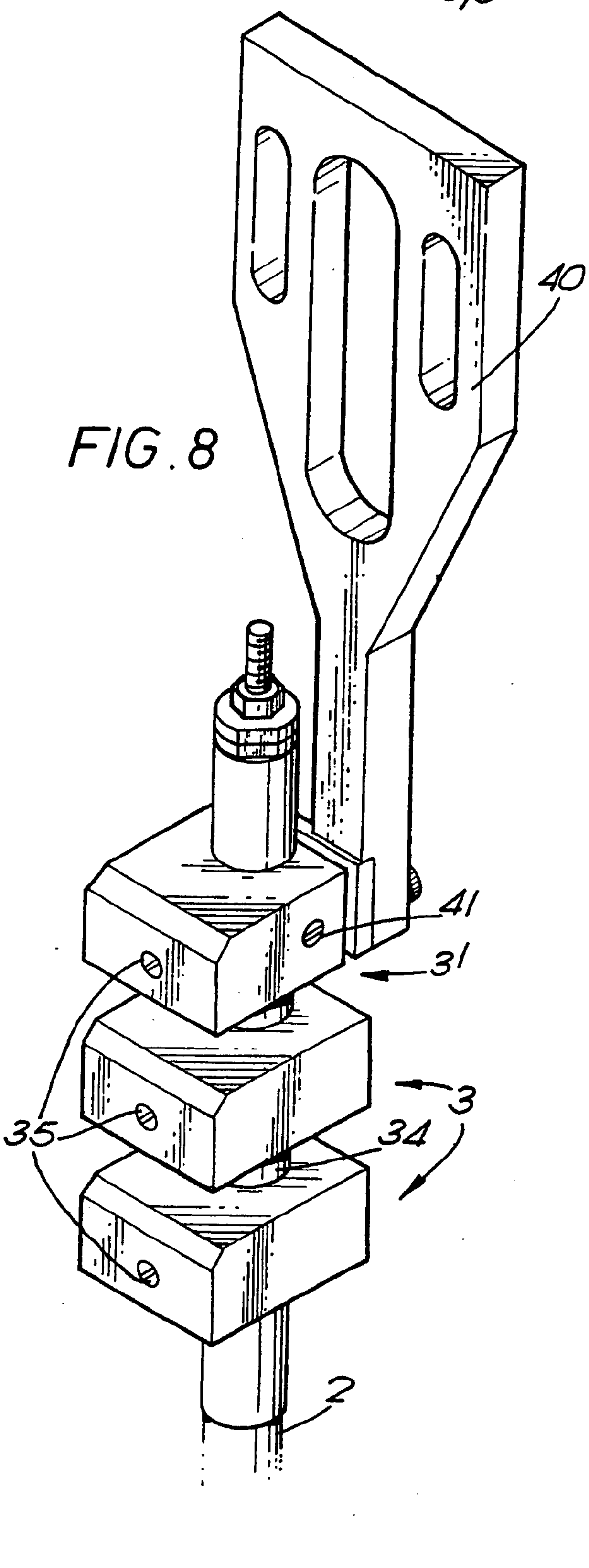
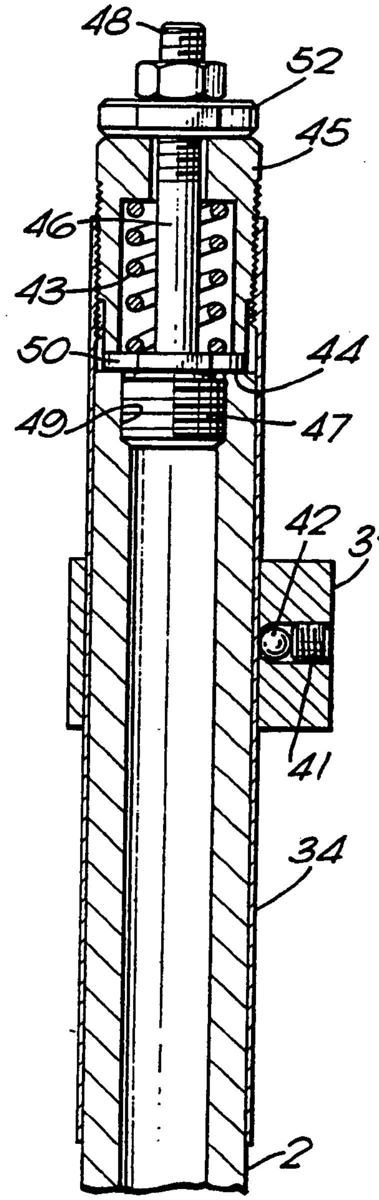


FIG. 9



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EXTERNAL FIXATOR DEVICE

This invention relates to a pin mounting block for an external orthopaedic fracture fixation apparatus and is more particularly, but not exclusively, concerned with a universal mounting block constructed so as to allow a pin carried by the block to have complete freedom of movement about at least two orthogonal axes.

Since the invention of the first external fixator recognisably similar to those in current use, clinical problems associated with their use, notably pin-tract infection and the complications caused by improper insertion of a pin have gradually been overcome and the advantages compared to plaster casting are now generally accepted. These may be summarised in better access to trauma site, earlier patient mobility and faster callus formation. The latter effect has been ascribed to the stimulus to bone formation caused by small motions at the fracture site and this has recently been demonstrated under controlled conditions where mechanical displacements were applied via the fixator.

A number of disadvantages have also been noted. Firstly, the high cost of a fixator of adequate stiffness to carry the entire body weight if necessary. Secondly, the observation that stiffness should ideally be related to body weight in some way and, thirdly, that in general fixators which meet the first specification tend to be bulky and heavy. Moreover, it has been noted that the external frame which carries the main load is opaque to X-rays and therefore obscures observation of the fracture site, and that current methods of monitoring the force exerted on the fixator tend to be unreliable.

GB-A-2157179A is concerned with a simplified pin mounting block or clamp for an orthopaedic fracture fixation apparatus. The block is stated to comprise

rotation, slide and housing elements nested one within the next, each element being apertured to receive a pin therethrough, and said rotation and slide elements respectively affording adjustment of said pin in azimuth and zenith on the one hand and height on the other hand relative to said housing elements, and a locking mechanism including a common actuator member operable simultaneously to lock said pin and said rotation and slide elements in said housing element. The block described in GB-A-2157179 does not have universal freedom of movement and, in use, does not provide the surgeon with a device which permits the pins to be inserted at unusual orientations which are not perpendicular or generally so, to the support element. The orientation of the pins may only be varied by relatively small amounts; moreover, longitudinal movement of the block is restricted by the length of the aperture of the housing.

According to the present invention there is provided an external orthopaedic fracture fixation device comprising an elongate support element and a universal pin mounting block which is mounted on the support element for receiving a fixator pin in a manner which permits variation of the orientation of the pin relatively to the mounting block and which permits rotation of the pin about the longitudinal axis of the support element, locking means being provided for securing the pin with respect to the support element in a selected orientation.

In normal use, the mounting block would be one of at least four such blocks provided on the support element, two of the blocks being disposed on each side of a fracture.

The present invention also provides a mounting block for use in a fracture fixation device as defined above.

In a preferred embodiment, the block comprises a housing, and the pin is supported on the block by a sliding element which is rotatable relatively to the housing about a transverse axis which lies in a plane perpendicular to the longitudinal axis of the support element. Preferably, the sliding element is displaceable along that transverse axis.

The housing preferably includes a bearing about which the block may rotate on the support element.

The position of the pin is variable with respect to the support element. In one embodiment of this invention, the variability of the pin position is achieved by virtue of the block being moveable longitudinally and rotatably on the support element and by virtue of the sliding element being received in a bore in the block, which bore lies in a plane perpendicular to the longitudinal axis of the support element. The pin may be securable in an aperture of the sliding element, whilst the sliding element may be securable to the housing.

Thus, in one embodiment of this invention, the locking means comprises means for locking the pin to the sliding element, means for locking the sliding element to the housing and means for locking the housing to the support element.

Conveniently, a sleeve is present around a length of the sliding element and the sliding element may be locked by pressure from outside the housing via the sleeve, which deforms under such pressure.

The device of the present invention may be modified in order to be capable of stimulating a healing bond fracture. This is achieved by uncoupling from the elongate support element the pin mounting blocks which are attached to, for example, the upper bond part above the fracture. The blocks are, therefore, able to slide longitudinally of the support

element. The uncoupled blocks are caused to oscillate longitudinally of the support element by linking the blocks to an oscillating arm. This in turn causes one part of the bone to move relative to the other and stimulates callus formation and healing.

According to a another aspect of the present invention there is provided an external fracture fixation apparatus comprising an elongate support element carrying a plurality of pin mounting blocks, said support element including an integral strain gauge element.

Preferably, at least two strain gauge elements are provided, and in a preferred embodiment of this aspect of the invention, four strain gauge elements may be provided in two opposing pairs.

According to a fourth aspect of this invention, there is provided an external orthopaedic fracture fixation apparatus comprising an elongate support element carrying a plurality of pin mounting blocks, said support element being made of a composite material.

Preferably, the composite material is a carbon fibre reinforced plastics (CFRP) composite.

For a better understanding of the present invention and to show how the same may be carried into effect, reference will now be made, by way of example, to the accompanying drawings in which:

Figure 1 shows an external fracture fixation apparatus in accordance with the present invention;

Figure 2 is an exploded perspective view of a pin mounting block in accordance with this invention;

Figure 3 is a plan view of the block shown in Figure 2;

Figure 4 is a plan view of a prior art clamp.

Figure 5 is a perspective view of the central portion of the support element of the fixation

apparatus shown in Figure 1;

Figure 6 shows the electrical circuit for balancing the signals from the strain gauge elements shown in Figure 5; and

Figure 7 is a diagrammatic view of the apparatus shown in Figure 1, modified for applying external stimulation to a fractured bone.

Referring to Figure 1, an external fixator 1 embodying all four aspects of the present invention is shown schematically. The apparatus in this configuration is regarded as the "standard configuration". The fixator 1 comprises a circular section support tube 2 which, in use, is arranged longitudinally and externally of a human or animal limb (not shown). The support tube 2 is made from an X-ray translucent material, for example a composite such as carbon fibre reinforced plastics (CFRP). The moment of inertia and stress-strain properties of the support tube should be adequate.

The support tube 2 is provided with a plurality of pin mounting blocks 3. In the embodiment shown, three blocks 3 are provided in a group toward each end of the support tube 2, each block 3 being slightly spaced from its neighbouring block 3 or blocks 3 in a group. Each block 3 is capable of carrying a bone pin 4 which, in use, is located in the bone of a patient. The pin 4 is clampable in the block and the block is capable of being clamped to the support tube 2.

Cemented to the support tube 2, at an intermediate region thereof are four strain gauges 5 (two shown). Wires (not shown) running internally of the support tube 2 connect to the strain gauges 5 and terminate in a plug (not shown) at one end of the support tube 2. Into this plug, a d.c. amplifier and recorder may be attached to determine the stresses which a healing bone is placing on the support tube 2.

With reference to Figures 2 and 3, the block 3 comprises a housing 6 which is fabricated from a light metal, such as aluminium. The housing 6 includes a first cylindrical aperture 7 which extends between the broad faces of the housing 6 and which has a diameter of such a size to receive the support tube 2 (not shown) in a sliding manner. The diameter of the main bore 7 is variable by opening and closing a slot 8. The width of the slot 8 is adjustable by a screw 9. Generally perpendicular to, and passing between, the two side faces of the housing 6 is a second bore 10 which is capable of receiving a sliding shaft 11 which, in turn, secures the pin 4. The sliding shaft is capable of being secured relative to the housing 6 by small screws 12 which pass through the housing 6 and communicate with the second bore 10.

The shaft 11 is not itself a snug fit in the bore 10 but is provided with a sleeve 13 which is made of a soft material, for example nylon. The sleeve 13 fits over a length of the shaft 11 and is received in the third bore 10 as a snug fit. The shaft 11 is then secured relative to the housing 6 by means of the screws 12 which, on tightening, tend to deform the sleeve 13 which bears on the shaft 11. The sleeve 13 may be disposable, a fresh sleeve being used for each new fracture to be treated.

The pin 4 passes through an aperture 14 in the shaft 11 and is held secured in place by the provision of a grooved washer 15 which, when tightened, bears on the pin 4, part of the periphery of the pin being received in the groove of the washer 15. The washer is tightened and held in place by a lock nut 16. In use, the pin may be secured against a shoulder 11A on the shaft 11.

In use, it can be seen that the housing is rotatable about the axis A and moveable longitudinally

of the axis A. Moreover, the shaft 11 is rotatable about axis B and moveable longitudinally of axis B. Accordingly, the pin 4 is universally orientable and is capable of being inserted into a bone at any convenient angle chosen by the surgeon. The system, therefore, bears similarities to a multi-lateral fixator system in which a number of external supports are provided.

Comparing the block of the present invention shown in Figure 3 with the prior art block shown in Figure 4, the universal nature of the block of the present invention can be seen. The prior art block 3P is not continuously rotatable about its support tube 2P. Moreover, movement of the pin 4P is restricted within the angle and also longitudinally of the block 3P. Finally the pin 4P is restricted from rotating to any substantial degree about the longitudinal axis L of the block 3P.

In Figure 5, four separate strain gauges 5 are arranged in a "two-active, two-dummy" bridge 20 configuration. Each strain gauge 5 is cemented to the support tube 2, preferably using an epoxy adhesive. The active gauges 5A are positioned diametrically opposite each other so that the axial strain may be sensed. The dummy gauges 5D are mounted at right angles to the active gauges for temperature and bending strain compensation. The bridge 20 is balanced by potentiometer R (see Figure 6) and the system is electrically compensated to remove any signals derived from bending moments on the support tube 2. An electrical voltage V is applied across the bridge 20 and output voltages S due to mechanical strain of the active gauges appear across the opposite corners of the bridge 20. The electrical wires to the bridge are routed through a small axial hole 21 in the support tube 2 and lead along the tube 2 to a terminating plug (not shown) to which d.c. amplifier and recorder may be

attached. The strain gauges 5 may be protected from damage and contamination by water-proof epoxy coating.

The fixator is precalibrated against a simulated bone fracture model with predetermined variable fracture stiffness so that measurements of strain in support tube 2, related initially to zero stiffness in the fracture zone, can be used to determine the degree of healing which has taken place.

Figure 7 illustrates how the apparatus shown in Figure 1 may be modified and connected up for micro movement of the separate parts of a fractured bone. This is known as the "stimulus" configuration. At the upper end of the support tube 2 there is provided a special block 30 which can be clamped rigidly using screw 31 in an angular position determined by the angular position of the blocks 3. A guide bar 32 is passed through an aperture (not shown) in the special block 30 and through another aperture (also not shown) in the uppermost block 3A and clamped by screw 33. Each of the three blocks 3 are then secured to each other on a tube 34 which passes through a bore (not shown) in each of the three blocks 3. The bore through which the tube 34 passes is in the same axial position as bore 7 shown in Figure 2. However, its external diameter is sufficient to accommodate the hollow tube 34. The tube 34 passes over the support tube 2 and is capable of sliding on the support tube 2. The clamping screws 35 are employed to hold the blocks 3 firmly to the tube 34. The blocks are, indirectly, secured to the special block 30 by means of the guide bar 32 and the tube 34. In this arrangement, each block 3 is released from security with the support tube 2 such that the blocks 3 are moveable longitudinally on the support tube 2, while being constrained axially by tube 34. At the upper end of guide 32 is a cylinder 36 containing a variable number of spring washers (not

shown) which may be arranged in different configurations to vary the overall stiffness. The pre-load on the springs can be varied by adjustment of screwed cap 37 and lock nut 38. The embodiment shown in Figure 5 has two purposes. Firstly, the upper special block 30 may be clamped to the support tube 2 and released from guide 32 in which case the entire axial load is carried on the spring stack in the cylinder 36 by virtue of the interconnection between blocks 3 by tube 34. Alternatively, the cylinder 36, spring stack, screw cap 37 and lock nut 38 may be removed and a connector 40 attached to the special block 30 to enable the upper set of blocks 3, when clamped to tube 37 which is released or slidable on support tube 2, to be oscillated by an external exciter (not shown) mounted to the connector 40. The oscillator is also fixed to the top of the support tube 2 and the upper special block 30 is released from security with the upper end of the support tube 2. This enables the oscillator to cause relative movement between the blocks 33 and the support tube 2. In order to allow the tube 34 to slide freely, the upper part of support tube 2 may be provided with a thin PTFE layer.

In Figure 8, there is shown a similar arrangement to that of Figure 7 in which the upper end of the support tube 2 carries three blocks 3 via an intermediate tubular element 34 which may be of stainless steel. Each block 3 is capable of being secured to the tubular element 34 by a pinch screw 35. The upper block 3' also has a second pinch screw 41 which can, when tightened, apply pressure to the tubular element 34 and lock the element 34 against the support tube 2, thus preventing movement of any of the blocks 3, 3' relative to the support tube 2.

However, when the screw 41 is released so that the tubular element 34 is slidable on the support tube 2,

the movement of the blocks 3, 3' relative to the support tube 2 can be controlled in one of two ways, both of which are shown in Figure 8, but only one of which would be implemented at any one time, depending on the amount and type of relative movement desired. Thus, relative movement may be permitted by a "passive" means in which a resilient means such as a spring is interposed between the upper block 3' and the support tube 2; this arrangement is shown in Figure 9 more clearly. Alternatively, relative movement may be achieved in an "active" manner by securing an oscillating means (not shown) to the upper block 3' by a connector 40. The oscillating means must, of course, also be connected directly to the support tube 2 so that relative movement may be achieved. Although, in the active arrangement, the spring arrangement (see Figure 9) can be removed, it is perfectly possible for the resilience of the spring to be overridden by the external oscillator and it may merely be necessary to loosen the pressure on the spring somewhat so that the oscillator need overcome only a relatively small residual force acting between the upper block 3' and the support tube 2.

In Figure 9, there is shown the upper end region of the support tube 2 shown in Figure 8; only the block 3' is shown. As described in relation to Figure 8, the tubular element 34 may be clamped directly to the support tube 2 by a screw 41 which acts via a ball bearing 42. When screw 41 is untightened, the block 3' is held securely to the tubular element 34 by another screw (not shown). As described above, a resilient means such as a spring may be interposed between the support tube 2 and the tubular element 34. Thus as shown in Figure 9, a compression spring 43 is provided which acts between an upper end 44 of the support tube 2 and an inner surface of a hollow, externally threaded

plug 45 which is screwed into the inside of the top end of the tubular element 34.

Extending through the plug 45 is a bolt 46 which is threaded at each end, the lower end 47 being somewhat enlarged relative to the upper end 48 so that it is able to be received in a thread 49 in the bore of the support tube 2. The bolt also includes a flange 50 against which the spring 43 abuts. At the upper end of the bolt 48 is provided a hexagonal nut 51 and a lock nut 52 against which the top of the plug 45 abuts. As shown in Figure 9, there is no gap between the flange 50 and the lower end of the plug 45. However, if the nuts 48 and 52 are loosened or if the plug 45 is screwed out of the tubular element 34 slightly, a gap between the flange 50 and the plug 45 will be created. As a load is applied between the tubular element 34 and the support tube 2, the spring is compressed and the support tube 2 and the tubular element 34 will move relative to each other. This load may be caused by, for instance, a patient walking.

CLAIMS

1. An external fracture fixation apparatus comprising an elongate support element carrying a plurality of pin mounting blocks, said support element including an integral strain gauge element.

2. A device according to Claim 1, comprising at least two strain gauge elements.

3. A device according to Claim 1 or 2, comprising four gauge elements arranged as two opposing pairs.

4. An external orthopaedic fracture fixation apparatus comprising an elongate support element carrying a plurality of pin mounting blocks, said support element being made of a composite material.

5. A device according to Claim 4, wherein the composite material comprises carbon fibre.

6. A pin mounting block for an external orthopaedic fracture fixation device, the block comprising a body which is mountable on an elongate support element of the fixation device and which receives a fixator pin in a manner to permit variation of the orientation of the pin relative to the body and to permit rotation of the pin about the longitudinal axis of the support element, the block being provided with locking means for securing the pin with respect to the support element in a selected orientation, when the block is in use.

7. A block according to Claim 6, wherein the pin is supported in the body by a sliding element which is rotatable relatively to the body about a transverse axis which lies in a plane perpendicular to the longitudinal axis of the support element, when the block is in use.

8. A block according to Claim 7, wherein the transverse axis is the axis of a bore in the body in which the sliding element is received.

9. A block according to Claim 7 or 8, wherein the sliding element is displaceable along said transverse axis.

10. A block according to any preceding claim, further comprising a bearing about which the block is rotatable about the longitudinal axis of the support element.

11. A block according to Claim 7 or any one of Claims 8 to 10 when appendant to Claim 7, wherein the locking means comprises means for locking the pin to the sliding element, means for locking the sliding element to the body and means for locking the body to the support element, when the block is in use.

12. A block according to Claim 8 or any one of Claims 9 to 11 when appendant to Claim 8, further comprising a sleeve which surrounds a length of the respective sliding element and supports the sliding element in said bore.

13. A block according to Claim 12, wherein the sliding element is lockable in the bore by pressure from outside the body via the sleeve, which sleeve deforms under pressure.

14. An external orthopaedic fracture fixation device comprising an elongate support element and at least four universal pin mounting blocks which are mountable on the support element and which each receive a fixator pin in a manner to permit variation of the orientation of the pin relatively to its respective block and to permit rotation of the pin about the longitudinal axis of the support element, locking means being provided for securing each pin with respect to the support element in a selected orientation.

15. A device according to Claim 14, wherein each block is movable longitudinally of the support element.

16. A device according to Claim 14 or 15, in which each block is in accordance with any one of

Claims 6 to 13.

17. A device according to any one of Claims 14 to 16, wherein the support element includes an integral strain gauge element.

18. A device according to any one of Claims 14 to 17, wherein the support element is made of a composite material.

19. An external orthopaedic fracture fixation device substantially as hereinbefore described with reference to the accompanying drawings (excluding Figure 4).